

**Amendment #1
to RFP-NIH-NIAID-DMID-03-09**

**"New Animal Models for: Part A Tuberculosis (TB) and Part B Invasive
Aspergillosis (IA)**

Amendment to Solicitation No.:	<u>NIH-NIAID-DMID-03-09</u>
Amendment No.:	1
Amendment Date:	July 9, 2002
RFP Issue Date:	April 29, 2002
Issued By:	Paul D. McFarlane Senior Contracting Officer NIH/NIAID Contract Management Branch 6700-B Rockledge Drive Room 2230, MSC 7612 Bethesda, Maryland 20892-7612
Point of Contact:	Ross Kelley, Contracting Officer
Name and Address of Offeror:	To All Offerors

The above numbered solicitation is amended as set forth below:

Part B: New Animal Models for Invasive Aspergillosis, NOTE 5 TO OFFEROR is replaced with the following:

NOTE 5 TO OFFEROR: For purposes of preparing a cost proposal assume that the contractor will be expected, over the life of the contract, to conduct research with the models of IA to answer at least 100 key scientific questions, where one question might represent a single gene product as a diagnostic target, that are submitted by the research community. Not all parameters may be tested in all models but rather shall involve the most appropriate model(s) to address a specific question. In addition, assume that two key personnel will attend a total of one other scientific meeting per year or that one key personnel will attend a total of two other scientific meetings per year to maintain interactions with the scientific community."

Part B: New Animal Models for Invasive Aspergillosis, item 3., of the Statement of Work is replaced with the following:

- 3) Optimize and refine, through consultation with the steering committee, existing small animal models of invasive aspergillosis to provide standardized model(s) suitable to address key scientific questions. To guide development of these animal models and to judge progress, the contractor shall, no later than three months after contract award, provide a list of detailed milestones, timelines and decision criteria to assess satisfactory completion of each milestone. These milestones will be developed together with the Project Officer and an expert panel of advisors. The expert panel of advisors will be established by the Project Officer with input from the contractor no later than three months after contract award.

New models shall:

- a) be based on currently accepted models of IA in mice and may include one larger species such as rabbits, and shall include pulmonary challenge;

- b) include neutropenic and immune-competent animals;
- c) in at least one, allow continuous blood sampling for the detection of surrogate markers of infection or disease;
- d) target survival times suitable to characterize surrogate markers of infection and disease progression (4-7 days);
- e) be able to differentiate among prior exposure, colonization and infection;
- f) allow reliable quantification of fungal burden by direct or indirect means and definition of surrogate markers of infection and disease progression, such as fever curves, detection of fungal metabolites etc. to overcome the limitations of quantitative organ cultures with filamentous fungi;
- g) allow assessment and quantification of growth dynamics of filamentous fungi;
- h) have the potential to be standardized;
- i) answer questions specific to different disease stages of IA, such as infection and dissemination, which may require development of separate models;
- j) shall be developed with *Aspergillus fumigatus* but also be suitable to evaluate virulence of various other *Aspergillus* species;
- k) consider the use of telemetry or infrared monitoring to establish fever curves;
- l) consider genomic information to develop molecular diagnostics approaches;
- m) employ molecular genetics and cloning strategies to target and evaluate specific *Aspergillus fumigatus* genes in the animal models to yield information about their role in survival and dissemination of the fungus in the host, host-pathogen interaction and host response to infection;
- n) be amenable to gene profiling studies at various stages of infection and during various stages of disease;
- o) be developed within a timeframe of approximately 2 years.

Except as provided herein, all terms and conditions of the RFP document NIH-NIAID-DMID-03-09 remain unchanged and in full force and effect.

The hour and date specified for receipt of offers is **NOT** extended.

Offerors must acknowledge receipt of this Amendment #1, by the following method:

- By acknowledging receipt of the amendment on each copy of the offer submitted.

Failure to receive your acknowledgment of this amendment may result in the rejection of your offer.

[Top](#) | [RFP-NIH-NIAID-DMID-03-09](#)

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